

### **In the Drawings**

The attached sheet of drawings includes changes to Fig. 7. This sheet, which includes Figs. 2 and 6-8, replaces the original sheet including Figs. 2 and 6-8.

Attachment: Replacement Sheet

## REMARKS

Claims 56, 59 - 66, 68 - 72 and 74 - 81 are pending in this application. Applicants thank the Examiner for allowance of claims 80 and 81. The drawings have been amended. No new matter has been added. In view of the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

The Examiner asserts that the drawings should be amended to show a catheter including first and second lumens extending therethrough from a proximal end of the catheter to a distal end, because Figs. 1 and 3 do not show what is claimed. It is respectfully submitted that new Fig. 7 shows a catheter 26 having first and second lumens 20 and 24 extending therethrough from a proximal end at hubs 38 to a distal end within a vessel 22. No new matter has been added. Thus, applicants respectfully request that the Examiner withdraw any objection to the drawings.

Claim 56 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. In view of the amendment to Fig. 7 and the above remarks, it is respectfully requested that this rejection be withdrawn.

Claims 56, 65-66 and 68-69 stand rejected under 35 U.S.C. 102(b) as anticipated by Fogarty et al. (U.S. Patent No. 4,564,014).

Claim 56 recites a system for establishing intermittent fluid communication with a patient's bloodstream comprising "a catheter including first and second lumens extending therethrough from a proximal end of the catheter to a distal end thereof, wherein, when in an operative position, the distal end of the catheter resides within a blood vessel of a patient" in combination with "*a first sealing balloon positionable within a distal end of the first lumen, so that, when inflated, the first balloon seals the distal end of the first lumen to prevent blood flow*

*thereinto*” and “a deflation mechanism for deflating the first balloon to reopen the first lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel.”

In contrast, Fogarty describes an apparatus for use in dilating occluded blood vessels having a tube 14 with a closed distal end which extends distally from a distal primary section 18 of a telescopic sheath 16. When the tube 14 is properly positioned as shown in Figs. 2-4 of Fogarty, internal fluid pressure in the tube 14 is increased to expand the tube 14, alleviating the occluded blood vessel. At no point does bodily fluid within the blood vessel ever enter the tube 14 or sheath 16. In fact, Fogarty states that the primary section 18 is proportioned to snugly receive the tube 14. *Fogarty*, col. 3, lines 18-20. Thus, it is respectfully submitted that Fogarty neither discloses nor suggests “a first sealing balloon positionable within a distal end of the first lumen, so that, when inflated, *the first balloon seals the distal end of the first lumen to prevent blood flow thereinto*” and “a deflation mechanism for deflating the first balloon *to reopen the first lumen to blood flow thereinto* while the distal end of the catheter remains within the blood vessel,” as recited in claim 56.

Claim 65 recites substantially similar limitations as claim 56 including “a balloon which, when inflated, physically contacts and seals the distal end of the lumen to prevent blood flow thereinto” and “a deflection mechanism for deflating the balloon to reopen the lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel.” Thus, it is respectfully submitted that claim 65 is allowable for at least the same reasons as claim 56. Because claims 66 and 68-69 depend from, and, therefore include all of the limitations of claim 65, it is respectfully submitted that these claims are also allowable.

Claims 59-64 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Fogarty in view of Burns (U.S. Patent No. 5,176,698).

Claim 59 recites a method of sealing a catheter indwelling within a vessel of a patient comprising the acts of “advancing a first deflated balloon along a first lumen of the

catheter to a position at least partially radially within a distal end thereof” in combination with “inflating the first balloon to seal the first lumen at the distal end thereof to prevent fluid from entering the distal end of the first lumen” and “purging the first lumen.”

As stated above, Fogarty neither discloses nor suggests either “inflating the first balloon to seal the first lumen at the distal end thereof to prevent fluid from entering the distal end of the first lumen” or “purging the first lumen.” It is respectfully submitted that Burns does not cure the deficiencies of Fogarty. Specifically, a balloon member 16 in Burns is disposed circumferentially around a distal end opening 47 of a shaft 14 and never seals/opens the distal end opening 47. In fact, the distal end opening 47 is permanently sealed to prevent proximal flow therethrough, only allowing gas from inside the shaft 14 to be expelled from therefrom. Thus, it is respectfully submitted that neither Fogarty nor Burns, either alone or in combination, discloses or suggests “inflating the first balloon to seal the first lumen at the distal end thereof to prevent fluid from entering the distal end of the first lumen,” as recited in claim 59. Because claims 60-63 depend from, and, therefore include all of the limitations of claim 59, it is respectfully submitted that these claims are also allowable.

Claim 64 recites limitations substantially similar to claim 59 including “inflating a balloon to seal the hollow interior passageway at a distal end of the catheter to prevent blood in the vessel from entering the hollow interior passageway.” Therefore, at least for the reasons described above with respect to claim 59, it is respectfully submitted that claim 64 is also allowable.

Claims 75-79 were objected to because they depended from rejected independent claim 59. In view of the above remarks, it is respectfully submitted that claim 75-79 are also allowable.

Claims 70-72 and 74 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Kipperman (U.S. Patent No. 5,092,839).

Claim 70 recites a system for establishing intermittent fluid communication with a patient's bloodstream comprising "first and second non-concentric catheters each of the first and second catheters including a lumen extending therethrough between proximal and distal ends thereof, wherein, when in an operative position, the distal ends of the first and second catheters reside within a blood vessel of a patient" in combination with "first and second balloons positionable within distal ends of the first and second catheters, respectively, so that, when inflated, the first and second balloons seal the respective distal ends of the lumens of the first and second catheters to prevent blood flow thereinto" and "a deflation mechanism for deflating the balloon to reopen the lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel."


In contrast, a balloon 14 described in Kipperman is used to dislodge a thrombus 32 from an occluded artery and to "shovel" the thrombus 32 into a coronary thrombectomy catheter 11. *Kipperman*, col 4 lines 52-62; Figs. 12-14. The balloon 14 remains inflated during withdrawal of the catheter 11 from the blood vessel so that the balloon 14 serves as a plug to prevent the captured thrombus 32 from entering the blood stream. *Id.* at col. 4, line 63 - col. 5, line 9. Because the balloon 14 of Kipperman stays inflated, it is respectfully submitted that Kipperman teaches away from "a deflation mechanism for deflating the balloon to reopen the lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel," as recited in claim 70. Because claims 71, 72 and 74 depend from and include all of the limitations of claim 70, it is respectfully submitted that these claims are also allowable.

## CONCLUSION

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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